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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/893,005 | 06/28/2001 | Hakuo Ikegami | IKEGAMI=2 | 6398 |

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| EXAMINER | |
|---|---|
| HELMER, GEORGIA L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1638 | |

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/893,005 | IKEGAMI ET AL. | |
| | Examiner | Art Unit | |
| | Georgia L. Helmer | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *11-16,18-21 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16,18-21 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) ~~Paper No(s)/Mail~~ Date. *13Sept2005*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2005 has been entered.

***Status of the Claims***

***2.*** Applicant has canceled claim 17, amended claims 11, 18, and 20, and added new claims 33 and 34. Claims 11-16, 18-21 and 32-34 are pending, and are examined in the instant action.

3. The § 1.132 Declaration of Shigeharu Fukuda dated 14 July 2005 is acknowledged and entered.

4. All rejections not addressed below have been withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112 second***

Claims 11-16, 18-19 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention, for

reasons of record. To the extent that this is a new rejection, the previous 112.2 rejection is extended to new claims 33 and 34, which depend on claim 11.

- In claim 11, line 1, "grown-up" is indefinite and ambiguous. A "grown-up" plant can be a plant at any stage from germinating seed to seed-set and senescence. Is this a flowering plant? Or a plant having seed?

Applicant traverses saying primarily: Applicant has amended claim 11 to recite that "the grown-up transgenic plant which is in a stage that is edible as a feed for mammals or edible as a vegetable or fruited plant for humans", and that "due to this amendment the "tobacco plant " specifically disclosed in Goodman is now certainly excluded from the scope of claim 11" (Response of 20 April 2005, p. 6).

Applicant's traversal is unpersuasive. The metes and bounds of "grown-up" are not apparent. The recitation of the limitation "a stage that is edible as a feed for mammals or edible as a vegetable or fruited plant for humans" is not substantially different from the rejected language "edible for mammals or humans". Furthermore, no specific definition is given by Applicant for the term "edible". The dictionary definition (Webster's Dictionary, 1994; p. 417) is "fit to eat". Certainly, mammals (goats, sheep, pigs) find tobacco fit to eat.

***Claim Rejections - 35 USC § 102***

6. Claims 11-16, 18, 20 and 32-34 are rejected under 35 USC 102 (b) as being anticipated by Goodman, et al (US #4, 956, 282, issued September 11, 1990), for

reasons of record. To the extent that this is a new rejection, the previous 112.2 rejection is extended to new claims 33 and 34, which depend on claim 11.

**The Declaration of Shigeharu Fukuda,** (Hereafter, "the Declaration") dated 14 July 2005, has been thoroughly considered and is found to be nonpersuasive.

**The Declaration** sets forth "[t[o demonstrate "a significant difference of the expression level of interferon-α between the transgenic plants according to the present invention and transgenic tobacco plants including the one" in the US 4,956,282 patent (hereafter "Goodman et al"), various experiments were done. See Declaration p. 2 , item 6. The Declaration documents the results of experiments on spinach transformed with interferon-α 2 (Genebank accession Y11834) and assayed for antiviral activity, celery transformed with interferon-α 2 (Genebank accession Y11834) and assayed for antiviral activity, cabbage transformed with interferon-α 2 (Genebank accession Y11834) and assayed for antiviral activity, potato transformed with interferon-α 2 (Genebank accession Y11834) and assayed for antiviral activity, and tobacco transformed with interferon-α 2 (Genebank accession Y11834) and assayed for antiviral activity.(Declaration p. 2-8). The Declaration concludes (p. 8, item 9) "as evident from the above experimental results, human interferon-α2 and human interferon-α8 were expressed in the transgenic spinach plant celery plant, cabbage plant , and potato plant according to the present invention in a yield of about 150-folds higher than the tobacco transgenic plants. This indicates that the transgenic plants according to the present invention are superior to transgenic tobacco plants in expression level when expressing human interferon-α2 in grown up plant bodies."

Applicant asserts that the presently claimed transgenic plant has a much superior level of expression (i.e., of human interferon-α2 when compared to the transgenic tobacco plant of Goodman) (Response, p. 7).

Applicant's traversal is unpersuasive, for reasons of record, as repeated in part below. Applicant has (via the Declaration) demonstrated the enablement of Goodman. Applicant's claims are not drawn to an improvement of Goodman. Applicant's claims (claim 11, lines 11-13) and all claims dependent thereon, are drawn to a transgenic plant comprising "a cytokine in an amount of 0.1 microgram to one milligram per one kilogram by fresh weight of the grown up transgenic plant". Applicant's method steps are identical to those of Goodman. Applicant 's starting materials are identical to Goodman's. Applicant did not specifically point to any evidence as to why Goodman is not enabling. Therefore, the percentage yield would have been an inherent property of the DNA construct used. If Applicant's percentage yields are different from that of Goodman, then the element(s) or step(s) resulting in such difference must be set forth in the claims to distinguish Applicant's invention to the prior art.

The scope of Goodman includes all plants other than seeds, which would encompass both "grown-up" plants and those which are not. Furthermore, while tobacco is one working example, Goodman specifically teaches edible plants, as previously indicated.

Accordingly Goodman anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

7. Claims 11-16, 18-21, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman, as discussed above for claims 11-16, 18, 20 and 32-34, in view of Genetically Manipulated Food News 2 June 2000 (www.intekom.com.tm info/rw00602, visited 7 December 2005).

The teachings of Goodman are discussed above. Goodman does not teach further supplementation with trehalose.

The addition of trehalose to foods is taught by Genetically Manipulated Food News 2 June 2000

which teaches that "trehalose has a potentially large market since is can be used as a component of sweeteners, seasoning, preserved and frozen food and soft drinks, and as a moisture retainer in cosmetics and a preservative in pharmaceutical products." (p. "11 of 17, 3rd full ¶ ). One of ordinary skill in the art would have been motivated to add trehalose to transgenic plants or plant extracts, with a reasonable expectation of success.

Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

***REMARKS***

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on Monday – Thursday at 10:30 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
December 7, 2005


PHUONG T. BUI
PRIMARY EXAMINER